



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,234	09/17/2003	Yijun Ruan	3240-0105	3948

6449 7590 04/28/2011
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
----------	--------------

1634

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

04/28/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/664,234

Applicant(s)

RUAN ET AL.

Examiner

DIANA JOHANSEN

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27,29,31-50 and 53 is/are pending in the application.
- 4a) Of the above claim(s) 1-24,42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-27,29,31-41,44-50 and 53 is/are rejected.
- 7) ☒ Claim(s) 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 12, 2010 has been entered.
2. The Amendment filed after final on August 12, 2010 has now been entered. Claims 33 and 37 have been amended. Claims 1-24 and 42-43 remain withdrawn (see below), and claims 25-27, 29, 31-41, 44-50 and 53 remain under consideration herein. As was noted in the Advisory Action mailed September 7, 2010, applicant's amendments to claims 33 and 37 overcome the prior rejection of those claims under 35 USC 112, second paragraph. However, these amendments also encompass new matter, as indicated below. Further, it is noted that the clarity of all of the claims has been re-evaluated in accordance with the "Supplementary Guidelines for Determining Compliance with 35 USC 112 and for Treatment of Related Issues in Patent Applications," 76 Fed. Reg. 7162 (09 Feb 2011), effective with respect to all applications as of February 9, 2011. As a result, new rejections under 35 USC 112, second paragraph have been applied with respect to all claims, as the current language of the claims does not render the metes and bounds of the claims sufficiently clear. Due to

the new grounds of rejection applied against claims 39-41, the previously indicated allowability of those claims has been **withdrawn**.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/restrictions

4. Claims 1-24 and 42-43 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 9, 2005.

5. With regard to the species election requirement previously applied with respect to claim 35, upon further consideration, that species election requirement is withdrawn.

Claim Objections

6. Claim 49 is objected to because of the following informalities: the claim states that "the type II restriction site is Mmel" (i.e., a particular enzyme) rather than, e.g., "the type II restriction site is a Mmel site" (or "Mmel recognition site"). Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

7. Claims 25-27, 29, 31-41, 44-50 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25-27, 29, 31-41, 44-50 and 53 are indefinite over the recitation of the limitation "the ditag"; see independent claims 25 (in (iii)), 26 (in (iii)), 39 (second line),

and 40 (second line), as well as dependent claims 41 (second line), 44 (second line), and 45 (second line). It is noted that each of the independent claims initially requires “at least one” ditag. Clear antecedent basis is lacking in the claims for the subsequent references to “the ditag,” as no single, particular ditag has previously been referenced. It is unclear whether the further limitations on “the ditag” apply to the previously referenced “at least one ditag” or whether some other scope or meaning is intended by the reference to only a single “ditag”. Because the metes and bounds of the claims are not made clear and definite, further clarification is required such that one of skill in the art could appreciate what activities would (and would not) infringe the claims.

Claim 31 is indefinite over the recitation of the limitation “to detect gene expression” in the phrase “determining the nucleotide sequence of the at least one ditag to detect gene expression”. The language “determining the nucleotide sequence” clearly requires the determination of the nucleotide sequence of the ‘at least one ditag’ previously referenced in the claims. However, it is not clear how the requirement “to detect gene expression” actually further limits the activities embraced by claim 31 (e.g., is this merely an intended result, or does this language impose further requirements on the manipulative steps and/or materials employed?). Accordingly, clarification is required.

Claim 32 recites the limitation “the ditag nucleotide sequence” in line 3. There is insufficient antecedent basis for this limitation in the claim, as the claims do not previously reference a “ditag nucleotide sequence”. It is further unclear what sequence or sequences corresponds to the limitation “the ditag nucleotide sequence”.

Claims 33-36 are indefinite over the recitation of the limitations "step (i)" and "step (ii)" in claim 33, because items (i) and (ii) are not previously described in the claims as "steps". Thus, clear antecedent basis is lacking for these limitations. This rejection may be overcome by either amending claim 33 to delete the term "step" or by amending claim 26 to employ that term (e.g., to recite "comprising the steps of").

Claim 37 is indefinite over the recitation of the limitations "step (i)" and "step (ii)" in the claim, because items (i) and (ii) are not previously described in the claims as "steps". Thus, clear antecedent basis is lacking for these limitations. This rejection may be overcome by either amending claim 37 to delete the term "step" or by amending claim 26 to employ that term (e.g., to recite "comprising the steps of").

Claims 39-41 are indefinite over the reference in the claims to "two joined first and second sequence tags" in claims 39-40. It is unclear whether this language requires two copies of "joined first and second sequence tags" or alternatively whether the word "two" simply references/describes the first and second tags (such that only a single copy of "joined first and second" tags is required). Accordingly, clarification is required.

Claims 39-41 are indefinite over the recitation of the limitations "the 5'-terminus sequence" and "the 3'-terminus sequence" in claims 39-40 because it is unclear what sequences are and are not embraced by this language. It is noted that the claims do not previously reference or define such sequences, and it is unclear what types of sequences are encompassed by and excluded by this terminology, such that the metes and bounds of the claims are not clear.

Claim 39 is indefinite over the reference in the claim to “each of the two tags”. The claim requires “two joined first and second sequence tags” wherein the first and second tags have particular characteristics (and it is reiterated that the limitation “two joined first and second sequence tags” is unclear for the reasons noted above). It is unclear whether the limitation “the two tags” references the “two joined” tags or whether the claim requires mapping “the first tag” and “the second tag”. Accordingly, clarification is required.

Claim 39 is also indefinite over the recitation of the limitation “the genome”. The claim does not reference any “genome” and it is unclear what genome or, e.g., what types of genomes correspond to the term “the genome” in the claims.

Claims 40-41 are indefinite because it is unclear what is encompassed and required by the “comparing” and “detecting” of the claims (see text of independent claim 40). With regard to the “comparing,” it is noted that at least one ditag of the claims is prepared via the “preparing” recited in claim 40, which results in the preparation of at least one copy of a particular type of nucleic acid molecule. However, the “comparing” of claim 40 requires comparisons of this molecule with a “genome map” and a “genome database”. It is unclear what is encompassed and required by this “comparing,” and it appears that at least some essential steps must be missing from the claims; for example, it is unclear how a physical nucleic acid molecule could be meaningfully compared with a database (rather, it would appear that one would require knowledge of the sequence of the molecule in order to achieve such a comparing). Further, it is not clear whether comparing with a “genome map” refers to or requires any physical step

(e.g., of mapping), or whether this "comparing" might also require or encompass a comparison of sequence information with map information. Thus, the boundaries of the "comparing" of the claims are not clear. Additionally, this indefiniteness renders the "detecting" of the claims unclear as well. While it would appear that "detecting no match on one or more databases" would require knowledge of a ditag sequence, no requirement to obtain such a sequence is mentioned in the claims (such that at least one essential step appears to be absent). Further, it is not clear what must actually be accomplished to achieve "detecting matching...on the genome map". Neither the claims nor the specification (nor the prior art) provide sufficient guidance to allow an ordinary artisan to recognize the boundaries of this claim limitation; it is not clear what would be considered as "matching," whether this detecting of "matching" requires a physical (or merely a mental) step, etc. Accordingly, the types of steps/manipulations required by claims 40-41 are unclear, and additional clarification is therefore required.

Claim Rejections - 35 USC § 112, first paragraph

8. Claims 25-27, 29, 31-38, 44-50, and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** It is noted that applicant's arguments of August 12, 2010 regarding the instant rejection were addressed in the Advisory Action mailed September 7, 2010.

Independent claims 25-26 each recite steps of producing "at least one full length coding sequence of a cDNA transcript" and subsequent steps of cleaving the produced "full length coding sequence". However, the originally filed specification does not provide basis for producing and cleaving such a full length coding sequence (or sequences) of a cDNA transcript. As previously noted, the response of December 29, 2009 points to at least paragraphs 12 and 14 of the published specification as providing support for these amendments. However, paragraph 12 discloses providing an isolated oligonucleotide comprising at least one ditag wherein the ditag may comprise a 5'-terminus sequence and a 3'-terminus sequence of a "nucleic acid molecule." Paragraph 14 then discloses that the nucleic acid molecule "may be the full-length sequence of a gene or a fragment thereof," citing as examples "full-length cDNA or cDNA". Thus, while this portion of the specification discloses providing ditags including 5'- and 3'-termini of full-length cDNAs, the "producing" and subsequent cleaving of "at least one full length coding sequence" of a cDNA transcript is not disclosed. Further, while a review of the specification reveals many similar disclosures of full length genes (e.g., paragraphs 14, 44, 48) and full length cDNAs (paragraphs 14, 52, 53, 56, 58, 90, etc.), no basis for producing/cleaving the "at least one full length coding sequence of a cDNA transcript" of the claims could be identified. Additionally, claims 33 and 37 as amended August 12, 2010 now reference and further limit this "cleaving" of "the full-length coding sequence of the cDNA transcript". Accordingly, applicant's amendments of both December 29, 2009 and August 12, 2010 (now entered) introduce new matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANA JOHANNSEN whose telephone number is (571)272-0744. The examiner can normally be reached on Monday-Friday, 8:30 am-2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571/272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634